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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,301	02/17/2000	Joseph C. Glorioso	204001	7569

7590 11/23/2001

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT PAPER NUMBER

1636

DATE MAILED: 11/23/2001

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/506,301	GLORIOSO ET AL.	
	Examiner	Art Unit	
	Gerald Leffers	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: _____ |

Lita Adams

DETAILED ACTION

Applicant's election with traverse of Group I (claims 1-16) in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the examiner asserted the claims are distinct because they have a different classification. It is further asserted that the examiner failed to demonstrate a serious search burden. This is not found persuasive because these arguments ignore the rationale provided in Paper No. 6 for why the inventions of the different groups are different and distinct from one another. For example, it was shown that the in vitro and in vivo methods of Groups II and III are biologically and functionally different from one another because they require steps which are not required in the methods of the other group and because the end results of the different methods are different. The compositions of Group I can be used in the different and distinct methods of Groups II and III. Also, the arguments presented in applicants' response ignore the fact that a showing of different classification is all that is required to satisfy the criteria of a burdensome search.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-20 are pending, with claims 17-20 withdrawn from consideration as being drawn towards a non-elected invention.

Claim Objections

Claims 1-16 are objected to because of the following informalities: the use of the acronym "HSV" without initially spelling out what the acronym stands for in claim 1 can be confusing. It would be remedial to amend the claim to recite "A recombinant herpes simplex virus (HSV)...". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of the phrase "...first adeno-associated virus (AAV) gene..." are unclear. The term "first" is confusing in that there is no limitation cited in the claim for additional AAV genes to be present. It would be remedial to amend the claim by deleting the term "a first" and substituting therefore the term "an". This does not render claim 9 indefinite in that the recitation of "a second AAV gene" remains clear.

Claim 1 is vague and indefinite in that the metes and bounds of the phrase "...adeno-associated virus (AAV) gene comprising a promoter and a polynucleotide encoding a rep protein..." are unclear. It is unclear as the claim is written whether the AAV "gene" necessarily comprises an AAV promoter operatively linked to the sequence encoding the rep protein. Upon reading the specification, it appears that the promoter can be a non-AAV promoter and that the only AAV sequence required to be present in the AAV "gene" is the sequence encoding a rep protein. It would be remedial to amend the claim language to more clearly indicate the minimal AAV sequences which need to be present in the recited AAV "gene".

Claim 2 is vague and indefinite in the metes and bounds of the term "derived from" are unclear. It is unclear the number and nature of the steps required to generate a "derivative" of a

Art Unit: 1636

rep polypeptide. It would be remedial to amend the claim by deleting the cited term and substituting therefore the term "obtained from".

Conclusion

Claims 1-16 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliot can be reached on (703) 308-4003. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.
Examiner
Art Unit 1636

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November 16, 2001

DAVID GUZO
PRIMARY EXAMINER
David Guzo